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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,609	03/25/2004	Heinz-Gerd Klaes	1/1479	7229

28518 7590 07/27/2007

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EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
07/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,609	KLAES ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-57* is/are pending in the application.

4a) Of the above claim(s) *21-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-20 and 42-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed 5/10/2007 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1 and 42 have been amended.

Claim 5 has been canceled.

Remarks drawn to rejections of Office Action mailed 1/12/2007 include:

Specification objection: which has been overcome by applicant's amendment and has been withdrawn.

112 1st paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

112 2nd paragraph rejections: which have been overcome in part by applicant's amendments and have been withdrawn in part.

103(a) rejection: which has been maintained for reasons of record.

An action on the merits of claims 1-4, 6-20, and 42-57 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The rejection of claims 4, 8-18, 45, and 47-56 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record.

Claims 4 and 45 recite the limitation "the compound of formula II is 3'-deoxy-3'-fluoro-5-O-[2-(L-valyloxy)-propionyl]guanosine" in the second line. There is insufficient antecedent basis for this limitation in the claim. It is noted that claim 1 requires the compound to be 2'-3'-dideoxy, which 3'-deoxy-3'-fluoro-5-O-[2-(L-valyloxy)-propionyl]guanosine is not. Applicants argued that formula II of claim 1 may also derive 3'-deoxy-3'-fluorothymidine because thymidine is substituted with a hydroxy group in only the 3'-position. That is, applicants stated that thymidine is inherently a 2'-deoxy compound and thus a 3'-deoxythymidine compound would have support from the 2'-3'-dideoxy compound of claim 1. This is found convincing for claims 2 and 43 (those containing thymidine), however, claims 4 and 45 are drawn to guanosine compounds, which are not 2'- or 3'-deoxy compounds. Thus claims 4 and 45 lack antecedent basis. Applicants note in their specification that 3'-deoxy-3'-fluoro-5-O-[2-(L-valyloxy)-propionyl]guanosine is a prodrug of 2',3'-dideoxy-3'-fluoroguanosine, however, the compound depicted is not 3'-deoxy-3'-fluoro-5-O-[2-(L-valyloxy)-propionyl]guanosine, but rather 2',3'-dideoxy-3'-fluoro-5-O-[2-(L-valyloxy)-propionyl]guanosine (see pages 9-10).

Independent claims 8-18 and 47-56 are drawn to compositions and kits comprising various agents, such as a further nucleoside reverse transcriptase inhibitor, a protease inhibitor,

an entry inhibitor, an integrase inhibitor, maturation inhibitors, antisense compounds, or non-nucleoside reverse transcriptase inhibitors, but fail to state what the actual additional compound is. The use of this functional language is seen to be indefinite as it does not allow a skilled artisan to know the metes and bounds of the claim. For example, if another artisan were to administer a composition having formula I and II in it, and an additional agent which has unknown properties, they would not know whether they were infringing on the instant claims or not, as the additional compound may or may not have any of the claimed functional characteristics. Per the MPEP:

> The second paragraph of 35 U.S.C. 112 is directed to requirements for the claims: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. There are two separate requirements set forth in this paragraph:
> (A) the claims must set forth the subject matter that applicants regard as their invention; and
> (B) **the claims must particularly point out and distinctly define the metes and bounds of the subject matter** that will be protected by the patent grant.

> Although an essential purpose of the examination process is to determine whether or not the claims define an invention that is both novel and nonobvious over the prior art, **another essential purpose of patent examination is to determine whether or not the claims are precise, clear, correct, and unambiguous**. The **uncertainties of claim scope should be removed**, as much as possible, during the examination process.
> The inquiry during examination is patentability of the invention as applicant regards it. If the claims do not particularly point out and distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under 35 U.S.C. 112, second paragraph. In re Zletz, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

The use of the functional language to define that which is included in applicants invention is not seen to clearly allow a skilled artisan to know the metes and bounds of the claimed subject matter, as not all compounds have been tested to see if they have any of the claimed characteristics. Moreover, in review of the specification to determine what applicant

defines these various functionally defined compounds as encompassing, it is noted that applicants use exemplary language to define that which they intend. Exemplification is not an explicit definition of anything as required by 112 2nd paragraph. If applicants are relying on the specification for a definition, the specification must clearly set forth the definition explicitly and with reasonably clarity, deliberateness, and precision. See ***Teleflex Inc. v. Ficosa North America Corp., 63 USPQ2d 1374, 1381 (Fed. Cir. 2002); Rexnord Corp. v. Laitram Corp., 60 USPQ2d 1851, 1854 (Fed. Cir. 2001);*** and MPEP 2111.01.

Applicants argue that the specification on pages 27-65 clearly enumerate the various agents encompassed by the various groups. However, as set forth previously, the specification uses exemplary language to define that which they intend, page 19 states "examples of further NRTIs are..."; "examples of protease inhibitors are...", etc. Exemplification is not an explicit definition of anything as required by 112 2nd paragraph. If applicants are relying on the specification for a definition, the specification must clearly set forth the definition explicitly and with reasonably clarity, deliberateness, and precision. See ***Teleflex Inc. v. Ficosa North America Corp., 63 USPQ2d 1374, 1381 (Fed. Cir. 2002); Rexnord Corp. v. Laitram Corp., 60 USPQ2d 1851, 1854 (Fed. Cir. 2001);*** and MPEP 2111.01.

All claims which depend from an indefinite claim are also indefinite. ***Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).***

Claim Rejections - 35 USC § 103

The rejection of claims 1-4, 6-20 and 42-57 under 35 U.S.C. 103(a) as being unpatentable over WO01/96338 (the '338 document) in view of WO88/00050 (the '050 document) is maintained for reasons of record.

The claims of the instant application are drawn to combinations of compounds of formula I and II for treating human retroviral and hepatitis B viral infections. Claims 2-4 and 43-45 limit the actual compounds. Claim 9 limits the amounts of agents. Claims 7-20 and 46-57 add additional agents to the composition.

'338 teaches the compounds of formula I and their use in treating viral infections (see abstract). What is not taught is the combination with the compounds of formula II.

'050 teaches the compounds of formula II and their use in treating viral infections (see abstract). What is not taught is to the combination with the compounds of formula I.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the compounds of formula I and II and the additional viral treating agents with these references before them. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. ***In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).*** (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also ***In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960)*** (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide

were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and ***Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992)*** (mixture of two known herbicides held prima facie obvious). In the instant case, the '338 document teaches that the compounds of formula I are effective as antiviral agents. The '050 document teaches that the compounds of formula II are effective as antiviral agents. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the art recognized agents to form a new composition which will be used for the very same purpose, an antiviral agent, with these references before them. One would have been motivated to combine these agents to form a new composition which would be used for the very same purpose, as an antiviral agent.

Applicants argue that the '338 document, which teaches compounds of formula I of the instant application, uses their compounds treating AIDS, ARC, and related diseases associated with HIV-1 infection; and the '050 document, which teaches compounds of formula II of the instant application, uses their compounds for treating retrovirus infections and HBV infections. As such, applicants state that it would not be obvious to combine the references as they are drawn to treating different diseases. Applicants then state that since their claims are for compositions for treating both retroviral and HBV infections. This is not found convincing. The '050 document teaches their compounds are effective for HBV as well as for HIV (see claim 1 for example). As such, the above logic still applies, as both compositions are individually taught for treating HIV, and as such, it would be obvious to combine them to form a new composition for the very same purpose. The intended use of the instant combination is not seen to impart

patentability to the combination rendered obvious by the prior art, as the combination of the prior art would still be able to be used for the very same purpose.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh
July 20, 2007

Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623